UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION : 01-CV-12257-PBS
	)	(Subcategory Docket: 06-11337)
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Judge Patti B. Saris
	)	Magistrate Judge Marianne B. Bowler

VEN-A-CARE'S SUR-REPLY TO ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

The arguments Abbott Laboratories Inc. ("Abbott") sets forth in its Reply in Support of its Motion for Summary Judgment ("Reply") have been addressed in Ven-A-Care's ("VAC") Response to Abbott's Motion for Summary Judgment ("Response"); and demonstrates only that there are genuine issues of material facts that cannot be decided on a motion for summary judgment. To clarify the record, VAC replies to several points Abbott has raised in its Reply.

I. VAC'S CLAIMS ARE NOT BARRED BY THE STATUTE OF LIMITATIONS

In accordance with this Court's order denying Abbott's motion to dismiss on statute of limitations grounds, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott*, Order dated March 14, 2008, Dkt. #4860 ("Order on MTD"), VAC's claims relating to all Ery drugs, dating back as early as 1995, are not barred by the statute of limitations because:

- VAC's pleading amendments relate back, on a drug-by-drug basis, to the initial Ery allegations in the first amended complaint filed under seal on February 15, 2001 ("2001 Complaint") because the amendments are grounded upon the conduct, transaction, or occurrence initially set out in the 2001 Complaint; and

- the FCA tolling provision applies.

See United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC et al., C.A. 08-cv-10852, 2009 U.S. Dist. LEXIS 92945 *21, 23 (D. Mass. Oct. 2, 2009) ("*Actavis*") (allowing VAC's allegations in a separate non-intervened AWP action to not only relate-back on a drug-by-drug basis but also holding VAC had "the right to invoke the provisions of the statute, including the tolling provisions").

A. VAC's Claims for Each Ery Drug Relates Back to the 2001 Complaint

VAC's claims for each of the 43 Ery drugs named in this case rightfully relate back to the 2001 Complaint. In arguing that the claims relating to Direct Prices and AWPs do not relate back, Abbott conveniently ignores VAC's allegations.

VAC's claims in the 2002, 2005 and 2007 amended complaints substantially arise from the same conduct, transaction or occurrence initially pled in the 2001 Complaint. VAC brought claims regarding Ery drugs in the 2001 Complaint founded upon allegations that false wholesaler prices had been reported by Abbott. In its 2001 Complaint, VAC described the different Medicaid drug reimbursement methodologies through the United States and specifically described how most Medicaid programs utilized AWP pricing in setting drug reimbursement. As explained in detail in the Response, VAC alleged a formulaic connection between AWP, Direct, and the root WAC prices and this connection establishes a commonality of wrongful pricing practices regarding all Ery drugs. The claims VAC added derived directly from the inflated and misleading wholesale pricing conduct which VAC initially pled. Accordingly, VAC's allegations all relate to the original Ery allegations and derive from the initially pled "conduct,

transaction or occurrence."[1] *See* Anderson Declaration Ex. 2 (First Amended Complaint filed 2/15/01 ¶¶ 31-32,38, 53, 56).

In its Reply Abbott argues that the three bases VAC proffers to support the argument that the claims added in 2002 and 2005 relate back to the 2001 Complaint are erroneous for the following disputed reasons:

(1) Abbott alleges that it is "factually false "that Direct Prices were set "at a level simply 5% greater than the false WACs." (Reply 2-4.) VAC proffers evidence to the contrary. (Response 7.)

(2) Abbott states that it was not its understanding that the compendia derived AWPs from WACs. (Reply 2-4.) VAC contends, and presents evidence supporting, that "AWPs were known by Abbott to be set as a function of WAC." (Response 7.)

(3) Abbott argues that the 2001 Complaint does not refer to AWP or Direct Price. (Reply 2-4.)[2] However, VAC clearly notes allegations regarding AWP and Direct Price. (Response 5-7).

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[1] Although it has made a clear showing, that its subsequent pleading amendments arise from the same Ery conduct, transaction or occurrence initially pled, VAC does not concede it must meet this precise threshold of same "conduct, transaction or occurrence" because as this Court noted in the *Dey* opinion, such a requirement is not explicitly a part of FRCP 15(c)(1) analysis. *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey*, 498 F. Supp. 2d 389, 398 (D. Mass. 2007).

[2] In footnote 1 of the Reply, Abbott inaccurately states that VAC's complaint only refers to "AWP" or "Direct Price" three times and that "[n]either term is used in ¶¶ 53, 56, 83, or 84, as Ven-A-Care inaccurately states on page 14 of its response." This is incorrect. In each of the paragraphs referenced, VAC's fourth amended complaint filed on August 30, 2007 ("Complaint") does describe how AWP and wholesaler pricing were utilized in Medicaid reimbursement. For example, in ¶53 the Complaint alleges:

> Abbott offered "contract pricing" to many of its customers that was less than "non-contract" or "Regular Cost" prices generally offered by wholesalers to any customer. Attached as Exhibit B is a print out from the Econolink software program for the wholesaler McKesson showing the AWP, Regular Cost and Contract Price. Ex B shows a "Contract Price" for Ery-Tab 250 MG which is less than the "Regular Cost." Abbott created inflated spreads on all the Drugs at issue for customers that purchased the drugs at Regular Cost, available to virtually any industry customer, and an even greater spread for those purchasing the Drugs "under contract".

Abbott raises genuine issues of material fact, which cannot be determined on a motion for summary judgment, thus, the motion should be denied.

B. Added Ery Drugs Share a Common Unique Pricing Structure and Relate Back to the 2001 Complaint

In analyzing the statute of limitations issue on a drug-by-drug basis, it is clear Ery drugs added in the current Complaint, which were part of the same ERY pricing scheme alleged in the 2001 Complaint, relate back to the 2001 Complaint.

In its Reply Abbott mischaracterizes VAC's arguments as follows:

(1) "Ven-A-Care's arguments about NDCs are irrelevant given that Abbott seeks judgment on a drug-by-drug basis." (Reply 4.) VAC makes no argument regarding NDCs.

(2) Abbott incorrectly characterizes the relation back standard VAC set forth, claiming that VAC argues that Ery formulations should be considered one drug because they all derive from the "same core erythromycin salt ingredient." (Reply 4.) This is not what VAC argues, VAC argues all Ery drugs named in this case are grounded in the same alleged pricing conduct, transaction, or occurrence. (Response 15-16.)

(3) VAC asserts "a blanket claim of fraud" which does not obviate the burden of proof as to each drug and cites no law to support such a standard. (Reply 4.) To the contrary, VAC's amendments are in line with federal case law supporting relation back.

In actuality, VAC argues all Ery drugs named in this case are grounded in the same alleged pricing conduct, transaction, or occurrence because Abbott published false WAC prices for each while it concealed the much lower gross invoice prices it normally charged to wholesalers. (Response 15-16.) This is consistent with the Court's statute of limitations ruling in another VAC case against Abbott in which the Court held, "subsequent amendments involving [certain drugs] properly relate back to the initial complaint . . . as each involves the same alleged pricing scheme for the same drug against the same defendant." *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott*, 538 F. Supp. 2d 392 (D. Mass. Mar. 13, 2008) ("*Abbott*")

Thus, the added Ery drugs relate back to the 2001 Complaint and summary judgment should be denied.

C. The FCA's Tolling Provision Extends the Statute of Limitations Such That VAC May Bring Claims From April 1994 To Present

The 2001 Complaint successfully tolled the running of the statute of limitations period.[3] Thus, VAC can recover as to all claims for fraudulent conduct relating to Ery beginning in April 1994, six years prior to the expiration of the limitations period.

Abbott argues VAC "presents no facts to show why the tolling provision should apply here – *i.e.*, that the facts material to its action were not known or should not reasonably have been known by the United States (or Ven-A-Care)," and that because VAC had "the ability to discover the facts that led to its claims" well before 2001, the tolling provision does not extend the statute of limitations. (Reply 5.)

However, as VAC explained in the Response, factual issues exist as to the extent, nature and meaning of what the government and relator had knowledge of. (Response 17-22.) Whether a relator may invoke the tolling provision of Section 3731(b)(2) is a question of material fact that is for the factfinder at trial to determine. *See Comm. of Massschusetts v. Mylan Laboratories,* Civ. A. No. 03-11865-PBS (D. Mass. Dec. 23, 2008) at 72 (declining to decide on a motion for summary judgment whether the government's claims as to certain additional drugs were timely-filed under the discovery rule of the Massachusetts False Claims Act, stating that it was "unclear on [the] record" and that the Court "will have to address statute of limitations . . . drug-by-

[3] The FCA's tolling provision extends the FCA's six year statute of limitations by allowing suits up to "3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b)(2). This Court has been clear, the tolling provisions of the FCA statute of limitations are available to relators in non-intervened cases generally and to this actual relator, VAC, specifically. *Actavis*, U.S. Dist. LEXIS 92945 at *30.

drug."); *see also Miller v. Holzmann*, 2007 U.S. Dist. LEXIS 15596, *21-26 (D.D.C. 2007) (The question of the level of knowledge the government had or should have had concerning the FCA violations was an issue of material fact "best adjudicated at trial by the jury;" the burden was on the defendant at trial to present evidence because the statute of limitations is an affirmative defense.). Thus, because there are material factual disputes between the parties regarding the application of the tolling provision to the statute of limitations, this is an issue better left for trial that should not be decided on a motion for summary judgment.

II. ALLEGED "GOVERNMENT KNOWLEDGE" DOES NOT PRECLUDE DAMAGES ACCRUING AFTER FEBRUARY 2001

As stated in the Response, many factual issues exist as to the extent nature, and meaning of Abbott's claimed "government knowledge." The evidence presented by Abbott does not reflect government knowledge. In this Court's ruling on a motion to dismiss in *Actavis* regarding the public disclosure bar, the Court addressed similar evidence and found that "government reports lack any suggestions of fraudulent activity by drug manufacturers or anyone else;" "[t]here is certainly no discussion or suggestion that AWPs are being used as part of a scheme to defraud the government, or any indication of how the scheme works." *Actavis*, U.S. Dist. LEXIS 92945 at *10. The Court continued, "neither the Defendants nor the drugs at issue in this case were revealed in the reports;" "[w]hich drugs and which manufacturers caused the averages to be at levels reported are not disclosed by any of the reports, and the Defendants and the drugs at issue are not readily identifiable by them." *Id*. at 11, 15.

Abbott's interpretation notwithstanding, the evidence does not amount to "government knowledge" and does not cut off damages as of 2001. VAC is confident that the evidence cited by Abbott is irrelevant and, even if admissible, insufficient; however, if any such showing is to be made, trial is the only appropriate arena.

III. GENUINE FACT ISSUES EXIST AS TO WHETHER ABBOTT IS LIABLE FOR "ANTI-KICKBACK" CLAIMS

In arguing summary judgment should be granted because VAC cannot establish a violation of the Anti-Kickback statute, Abbott mischaracterizes VAC's allegation stating, "an allegation of an 'awareness' of the 'potential' to market the spreads is insufficient;" and ignores evidence VAC offers to support its allegations of anti-kick back liability by improperly stating, "Ven-A-Care offers no proof that Abbott marketed the spreads on it Ery products." (*Id*.)

VAC properly pled these claims by alleging, *inter alia*, that Abbott not only caused the publication of inflated and misleading prices, but also "knowingly used the spread as an unlawful inducement." *See* Anderson Dec. Ex. 7 (Ven-A-Care's Complaint ¶¶49-70.) Not only did this pleading satisfy this Court's previously stated pleading threshold for these types of claims, *In re Pharm. Industry Average Wholesale Price Litigation,* 491 F. Supp. 2d 12, 18-19 (D. Mass. 2007) ("*Abbott*"), VAC's allegation regarding the anti-kickback claim already impliedly satisfied the pleading threshold here, as this Court did not dismiss the claim at the motion to dismiss stage. *See* Order on MTD.

Furthermore, VAC has set forth significant evidence to support its allegations, including:

- Abbott knew pharmacies were interested in relative reimbursement between generics,
- Abbott knew its published prices were a part of the reimbursement calculations, and
- Abbott actively communicated or enabled the communication of reimbursement information, such as AWPs for its drugs, to be compared with actual pharmacy prices to pharmacies via retail buying group correspondence, price change notification fax blasts, price reporting to pricing compendia, and pharmacy operation software tools.

(Response 22-24.) As this Court noted, anti-kickback liability will be "highly fact specific." *Abbott*, 491 F. Supp. 2d at 19. In light of VAC's sufficient allegations and supporting evidence,

summary judgment is not appropriate as there are genuine issues of material fact that should be presented to the fact-finder at trial.

IV. DAMAGES ARE BASED ON INFLATED ERY DRUG PRICES AND APPROPRIATELY DERIVED FROM DUGGAN'S ECONOMIC EXTRAPOLATION

A. VAC's Damages Are Based on Inflated Ery Drug Prices Reported By Abbott

The statement that VAC "does not dispute that the reported prices about which it complains did not cause the Medicaid payments at issue" is simply false. (Reply 12.) The false claims VAC alleged are predicated on an underlying fraudulent pricing scheme and Abbott is thus chargeable with causing false claims to be presented. VAC proffered sufficient evidence to demonstrate the government would not have paid Medicaid claims at the inflated amounts had Abbott not made or caused to be made false statements. *See* Dkt. #6417 (VAC SOF in Support of VAC's MPSJ at ¶¶51-53). The prices, reported and concealed, are the subject matter of the false statements and the source of the government's loss. (*Id*.)

Abbott hangs it hat on the holding in *California, ex rel. Ven-A-Care of the Fla. Keys., Inc. v. Abbott Labs., Inc.*, 478 F. Supp. 2d 164 ("*California Abbott*") (D. Mass. 2007) in arguing that the entire premise of VAC's case collapses when a state uses a "lesser of" (aka "lower of") formula for reimbursement. Essentially, Abbott argues that VAC's recovery of damages for its claims are based on something other than a "compendia-reported price;" thus, it is impossible for Abbott to increase its market share by manipulating reported prices, and VAC's case collapses. (Reply 12.)

As VAC details in the Response, this case is distinguishable from *California Abbott*. Additionally, VAC's damages calculations are clearly connected directly to Abbott's alleged pricing conduct because VAC only seeks damages where the given Medicaid programs' "lesser

of" formula would have calculated reimbursement based upon the truthful Abbott prices which Abbott previously concealed. (Response 24-26.) The mechanics utilized in setting any FUL/MAC are irrelevant given that VAC has refined its allegations and is only pursuing the above-discussed claims. VAC's approach to damages is appropriate and in accordance with what this Court has already found in *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 98 (D. Mass. 2007), where the Court held that, "if BMS had reported a true AWP for its branded multi-source drugs, Medicare would have reimbursed based on that branded drug's AWP, rather than the inflated median, and plaintiffs would have paid less."

B. Dr. Duggan Made Appropriate Economic Extrapolations in Calculating Damages

Abbott simply restates, and not surprisingly cites no case law in support of, the arguments it set forth in its initial motion, that Dr. Duggan's extrapolations are unreliable because he only used actual claims data for his computations for 15 of the 49 states. (Reply 13.) Specifically, Abbott claims the extrapolations are unreliable because (1) Dr. Duggan did not use or have available some state claims data for every state and thus, did not rely on actual claims data from every state, and (2) failed to consider nuances of each states' reimbursement policies.

As stated in the Response, with supporting case law:

> Extrapolation is a reasonable method for determining the number of false claims, if the statistical methodology is appropriate. Estimates based on representative sampling can be used when a precise computation is technically possible but logistically impossible. Further, failure to include all possible factors in a reasonable estimation of damages is not fatal.

Response 29 (citations omitted). In response to Abbott's contentions:

(1) "All of Dr. Duggan's damage calculations, *even the extrapolated portions*, were rooted in actual claims data and were quite conservative" and the state data used represented the majority of all Mediciad spending on the 43 Ery drugs because Medicaid spending and the total number of claims is typically highest in a limited number of states, Dr. Duggan was able to cover most aggregate spending by using state data for only 15 state Medicaid

programs. Furthermore, Dr. Duggan confimed the accuracy and reliability of his state data calculations. (Response 29-30.);.

(2) The "failure to include all possible factors in a reasonable estimation of damages is not fatal." *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 732 (N.D. Ill. 2007).

CONCLUSION

For the foregoing reasons and for the reasons set forth in Ven-A-Care's Response to Abbott's Motion for Summary Judgment, Ven-A-Care requests that the Court deny Abbott's Motion for Summary Judgment.

Respectfully submitted,

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CERTIFICATION OF SERVICE

On December 18, 2009, I caused an electronic copy of the VEN-A-CARE'S SUR-REPLY TO ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT to be served on all counsel of record via electronic service pursuant to paragraph 11 of the Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ C. Jarrett Anderson
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